I. The Office Action

The August 28, 2006 final Office Action (the "Office Action") in this application:

1.) rejects claims 1-3 and 8-9 under 35 U.S.C. 102(b);

2.) rejects claims 1-2, 6-8, 12-13 and 22-26 under 35 U.S.C. 102(b); and

3.) rejects claims 14 -15 and 17-21 under 35 U.S.C. 103(a).

Applicants request continued examination (RCE) and reconsideration of the instant application in light of the amendments and remarks submitted herein.

II. Amendments to the Claims and Cancellation of Claims

Support for the recitation of "uniform spacing of the first plurality of perforations defines a first injection density" and "uniform spacing of the second plurality of perforations are different from the uniform spacing of the first plurality of perforations and thereby define a second injection density" in claims 1, 8 and 25-26 can be found at least, for example, in figure 3 and in the narrative at page 22, line 26 to page 23, line 6.

Claims 6 and 7 are amended to properly refer to the "device" recited in the preamble of the independent claim from which they depend. Claim 7 is amended to depend from claim 1 instead of claim 6.

Claim 8 incorporates the limitations of claims 9 and 12. Accordingly, claims 9 and 12 are cancelled without prejudice or disclaimer to prosecution at a later date. Claims 13 and 24 are also hereby cancelled without prejudice or disclaimer to prosecution at a later date, in light of amendments to the claims.

III. Rejection of claims 1-3 and 8-9 under 35 U.S.C. 102(b)

The Office Action rejects claims 1-3 and 8-9 under 35 U.S.C. 102(b) as being anticipated by Gardiner (U.S. Patent 4,228,796). Applicants traverse the rejection.

The disclosed insulin injection guide of Gardiner provides a single plurality of apertures through which insulin administration is directed. As indicated in col. 1, lines 29-38, the particular problem with which Gardiner is concerned with is adverse conditions which can result from *repeated* daily injections of insulin at the same location. Therefore, Gardiner discloses an insulin injection guide so that injections are not administered to the same position everyday ("Since an insulin injection must be received daily…", at col. 1, line 19), that is, the guide serves to remind a user where the previous day's injection was administered, so that the next injection is administered to another area, i.e. through a different hole or even a different thigh (col. 3, lines 36-42).

There is no disclosure or suggestion in Gardiner relating to spacing between distinct pluralities of perforations in the guide, or more particularly, uniform spacing of perforations of a first plurality of perforations and uniform spacing of perforations of a second plurality of perforations, where the uniform spacing of the perforations of the first plurality of perforations *is different* than the uniform spacing of the second plurality of perforations. There is no teaching or reason, based on the device's intended use (insulin injection guide) or its drawings/disclosure, to artificially parse out the single plurality of illustrated perforations of the device into multiple pluralities, except through a hindsight reconstruction based on the instantly recited limitations.

The disclosure and device of Gardiner does not consider or even contemplate particular injection location densities because injection density of insulin is a non factor in admisnitering insulin, as insulin injection employs one

needle per injection session. Administration of insulin can be to an arm, leg abdomen or buttock, for example, so that injection is not to the same site. Insulin needle injection/systemic treatment provides insulin for absorption into the bloodstream and eventually to the cells of the body to facilitate glucose entry into cells so that they can use the glucose for energy. This is entails a single injection of insulin per administration. Contrarily, the instantly claimed guide is utilized to mark out a particular array/pattern of injection density for multiple injections of a locally active composition, (e.g. botulinum toxin) that treats hyperhydrosis by reducing the production of sweat by sweat glands are spread out over the injection/treatment site.

An aspect of the instantly claimed device provides a user with first and second pluralities of perforations, the first and second pluralities of perforations defining different injection densities (page 23, lines 1-6 of the instant specification).

Contrarily, the pluralities of perforations in Gardiner cited by the Office Action (first plurality of perforations labeled Mon, Tues, Wed and Thurs and the second plurality comprising three perforations labeled Fri, Sat and Sun, see page 3 of the Office Action) are not grouped, defined or specified in Gardiner as separate pluralities. There are no pluralities suggested or explicitly disclosed in Gardiner, and accordingly nor are differences between uniform spacing within the perforations of each of these artificially Office Action parsed multiple pluralities. This is not surprising, *as there is no need for such considerations* when utilizing an insulin injection guide, which is provided in order to simply avoid repeating a single injection of insulin at the same area day after day, whereas the instantly claimed device assists hyperhydrosis therapy. Hyperhydrosis therapy (lowering sweat production over a localized, injected area) requires quite a different approach than regulation of blood glucose levels (multiple injections of a local acting botulinum toxin, as opposed to a single injection of insulin that results in systemic distribution, respectively).

Clearly, Gardiner does not disclose each and every element of independent claims 1 and 8 and thus does not anticipate the claimed device. Dependent claims 2-3 and 9 recite limitations that further differentiate the invention over Gardiner.

The rejection to claim 9 is moot in light of its cancellation.

Thus, this rejection should be withdrawn.

IV. Rejection of claims 1-2, 6-8, 12-13 and 22-26 under 35 U.S.C. 102(b)

The Office Action rejected claims 1-2, 6-8, 12-13 and 22-26 under 35 U.S.C. 102(b) as being anticipated by Whitmore, III et al. (U.S. Patent 6,036,632). Applicants traverse this rejection.

The Office Action asserts that the device disclosed in Whitmore, III includes a first group of perforations (columns) spaced apart by a uniform distance, and a second group of perforations (rows) spaced apart by a second uniform distance that is not equal to the first. No arrangement or hint of such an arrangement disclosed in this document.

Whitmore, III et al. discloses *one* set of perforations, wherein all of the perforations in the one set of perforations are uniformly spaced from each other. There is no disclosure, implicitly or explicitly provided, that teaches or suggests a device for assisting hyperhydrosis therapy having non-overlapping first and second plurality of perforations, wherein the uniform spacing of the first plurality of perforations defines a first injection density and uniform spacing of the second plurality of perforations are different from the uniform spacing of the first plurality of perforations and thereby define a second injection density and wherein the first and second plurality of perforations extend completely through the material from the upper face to the lower face, as presently claimed.

It appears that the Office Action is not considering the instantly claimed invention as a whole, as well as the cited art as a whole, but is rather taking the instant limitations as puzzle pieces to be matched to atomized prior art references (hindsight reconstruction). A reading of Whitmore, III et al., *alone and without knowledge of the instant claim limitations*, would not reveal or suggest a first and second plurality of perforations, let alone a first uniform distance between perforations of the first plurality and second differing uniform distance between perforations of the second plurality as recited in the instant claims. The

current amendments even further define the invention over the cited reference. These elements are not found in Whitmore, III et al. Dependent claims 2, 6, 7, 12, 13, 22 and 23 further recite limitations that define the instantly claimed invention over Whitmore, III et al.

The rejection of claims 12, 13 and 24 are moot in light of their cancellation.

Thus, this rejection should be withdrawn.

V. Rejection of claims 14-15 and 17-21 under 35 U.S.C. 103(a)

The Office Action rejects claims 14-15 and 17-21 under 35 U.S.C. 103(a) as being unpatentable over Walker (US2002/0086036) in view of Gardiner U.S. Patent No. 4,228,796). Applicants traverse this rejection.

The Office Action asserts that Walker discloses all aspects of the claimed invention with the exception of the use of a device having a plurality of perforations (Office Action, page 5). Respectfully, the Office Action has misconstrued the disclosure of Walker, as well as Gardiner, utilizing impermissible hindsight to combine these two references and derive therefrom the presently claimed method for assisting hyperhydrosis.

Walker discloses at paragraphs 0087-0088 identification of a field of hyperhydrosis, by utilizing the Minor's iodine starch test, which turns a sweating skin area blue. The perimeter/boundary of this skin area is then marked of with a pen (i.e. demarcated) and botulinum toxin administered within this field, here a 8X10 $cm^2$ area. The Office Actions statement "…injecting botulinum toxin at the location of the mark.", Office Action, page 5) should more accurately be "to inject the field/area within the border/perimeter that has been demarcated according to the iodine-starch test". There is no indication of markings of a particular pattern or specific points for botulinum injections indicated by an iodine-starch test, but rather a field of sweating skin, clearly unlike the marking by extending a marker through perforations, a step positively recited in claims 14-15.

There is no mention in Walker of placing in contact with the dermal area, determined to exhibit hyperhydrosis, a lower face of a device which includes a material with an upper face and a lower face and having a plurality of perforations which extend completely through the material from the upper face to the lower face extending a marker through a perforation so as to mark a dermal surface under the lower face of the material removing the device from contact

with the dermal area; and administering a botulinum toxin to more than one marked dermal surface per each administration session, as presently claimed. Walker discloses determining the sweating area, demarcating the perimeter, and administering toxin therein. There is no disclosure regarding the claimed placing step, the extending and marking step, removing step and subsequent administering step to more than one marked dermal surface per each administration session, as positively recited in claim 14, for example. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). No such desirability is found to combine Walker with Gardiner.

Turning to Gardiner, the insulin injection device is not disclosed or suggested to be used as a template for marking at all, let alone a dermal area determined to exhibit hyperhydrosis. This is not surprising because insulin is administered as a single injection, and not as a series of simultaneous proximate injections such that there is a concern regarding distances between injections having an effect on treatment results (contrary to botulinum toxin administration to treat hyperhydrosis where multiple, evenly-spaced injections desired).

Hyperhydrosis therapy relies on effective coverage of the overactive sweating area to provide effective treatment, whereas insulin can be injected practically at any location on the body, as a single injection, thus there is inherently no consideration/reliance on adjacent, even spacing between multiple injections. Combination of prior art with different principles of operation is impermissible. The *device and associated principle of operation* in Gardiner is concerned with injection of insulin *at the same site* day after day, not with marking a dermal surface and subsequently administering botulinum toxin to more than one marked dermal surface per each administration session, nor to treating a dermal area, as disclosed in Walker.

It is only by taking the instant application and claims as a roadmap to find, combine and derive the presently claimed method steps from these two disparate references that the Office Action arrives at its assertion of obviousness. One has to look no further than the Office Action itself to see the differing principles of operation in these two references which do not lend themselves to their combination in absence of the suggestion provided by having the instant claims in hand. In the last paragraph on page 5 of the Office Action, it is stated that it "…would be obvious to one of ordinary skill in the art at the time of the invention to employ the device of Gardiner in the method for assisting hyperhydrosis therapy of Walker to allow for the marking of areas that need to be injected and identification of areas that have already been injected.". This statement relates to the principles of operation of the device in Gardiner, and has nothing to do with the instantly claimed method steps and device utilized in association with the claimed methods (claims 14-15 and 17-21) nor Walker. The instant device is used to provide a pattern of injections points for "administering a botulinum toxin to more than one marked dermal surface per each administration session", as claimed, not marking of areas that need to be injected and identification of areas that have already been injected, *it marks areas to be injected.*

In Gardiner, there is no mention of hyperhydrosis or methods to treat or utilized the device disclosed therein in hyperhydrosis therapy. Walker does not mention utilization of any device to mark more than one dermal surface for administration of a botulinum toxin to the more than one marked dermal surface per each administration session. Furthermore, there is no suggestion or disclosure regarding injecting a botulinum toxin to the dermal area through more than one of the perforations of the device per each injection session, as presently claimed (claim 17). In fact, Gardiner *teaches away* from such a step, teaching only single administration/injection through only *one* hole of the guide "after the guide 10 is placed on the leg, *the proper hole* is selected and the user administers an injection to his thigh through *the selected hole*." (col. 3, lines 2-4, emphasis added). Note the reference to a single hole and thus single injection.

A reference which teaches away from a claimed invention cannot be used to reject a claim (*W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) ("…the district court erred in…disregarding disclosures in the references that diverge from and teach away from the invention at hand." 220 USPQ at 311). Again, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990).

Thus, this rejection should be withdrawn.

VI. Conclusion

All issues raised in the Office Action have been addressed. Reconsideration and allowance of claims 1-3, 6-8, 14, 15, 17-23, 25 and 26 is requested.

The Commissioner is hereby authorized to charge any fee(s) required or necessary for the filing, processing or entering of this paper, petition for Request for Continued Examination (RCE) or any of the enclosed papers and to refund any overpayment to deposit account 01-0885.

Respectfully submitted,

/Claude L. Nassif/

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